



Lab US Realm Closing Ceremony

Office of the National Coordinator for Health IT and HL7 Orders and Observations

April 18, 2017



Meeting Etiquette

- » All attendees will be muted when they enter
- » Speakers and support team members will be promoted to panelists
- » If you have any questions or comments, please submit them in the **Chat** box (not the Q&A) and send to “**All Panelists**”
- » This meeting is being recorded and will be archived on the Lab US Realm Wikipage, under “Meeting Notes”



Agenda

Opening Remarks

- » **Steven Posnack, MS, MHS**, Director, Office of Standards and Technology

Initiative Summary

- » **Bob Yench**, Initiative Technical Lead
- » **Hans Buitendijk, Riki Merrick, Freida Hall**, Co-Chairs

Looking Forward

- » **Farrah Darbouze**, Public Health Analyst, Office of Standards and Technology

Closing Remarks

- » **Farrah Darbouze**, Public Health Analyst, Office of Standards and Technology

Opening Remarks

Steven Posnack, MS, MHS, *Director, Office of Standards and Technology*

Initiative Summary

Bob Yench, *Initiative Technical Lead*

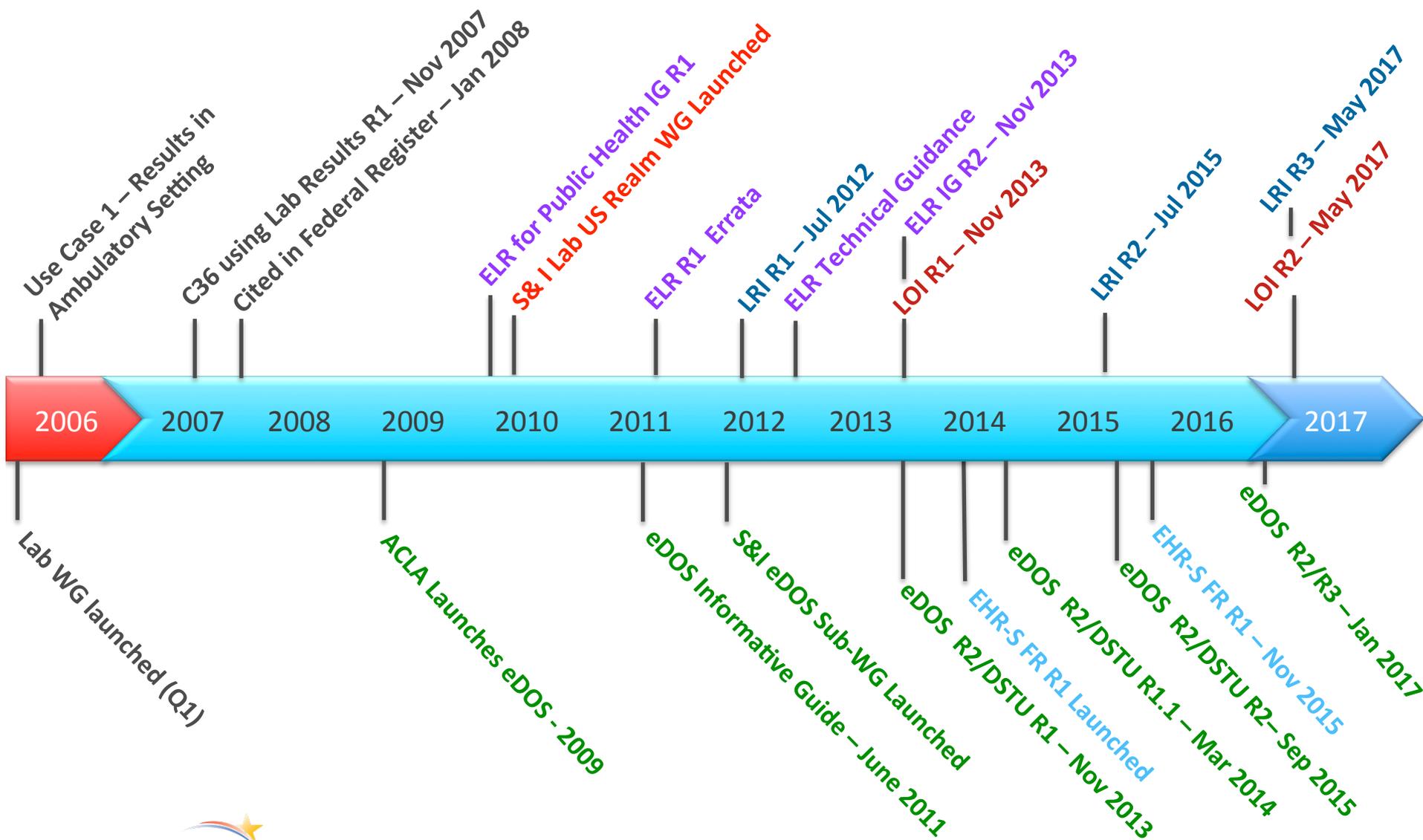
Hans Buitendijk, *Co-chair*

Riki Merrick, *Co-chair*

Freida Hall, *Co-chair*

Initiative Summary

Lab US Realm Timeline and Activities



Initiative Summary

Goals of Lab US Realm

The Lab US Realm activities have roots in the HITSP Lab WG launched in Q1 2006

ONC empowered the laboratory community to establish a national standard for reporting laboratory results in ambulatory care in support of [Executive Order 13410](#) that:

- » Supports all CLIA reporting requirements
- » Harmonizes use of LOINC, SNOMED, UCUM
- » Reduces the number and complexity of interfaces required by trading partners
- » Moves towards “interoperability out of the box” by removing ambiguity in current specs and constrain optionality in base HL7 V.2
- » Incorporates support for public health reporting
- » Harmonizes data element definitions with other health IT content specifications to ensure patient data can move where and when needed across any exchange model
- » Provides for the security and confidentiality of patient data
- » Builds on existing standards (HL7)

Initiative Summary

Goals of Lab US Realm

To achieve the stated goals, the community, with insights from the California Health Care Foundation's (CHCF) EHR-Laboratory Interoperability And Connectivity Specification (ELINCS) project and participation from the Integrating the Healthcare Enterprise (IHE) lab community, undertook a major collaborative effort to:

- » Establish common and universal minimum requirements for all results exchanges in ambulatory care setting for the US Realm
- » Canvas the standards landscape and identify, assess, and select best fit for the requirements
- » Identify and address gaps in selected standards, vocabularies, value sets, and ancillary standards
- » Identify and harmonize vocabulary requirements across actors and exchange scenarios

The effort culminated in the development of the “Health Level Seven (HL7) U.S. Realm - Interoperability Specification: Lab Result Message to EHR (ORU^R01) (HL7 Version 2.5.1) September, 2007”

- » Primary standard in HITSP C36 Lab Results Component
- » First step in strategy for “round-trip” suite of specifications
- » First laboratory IG specified in Federal Register (January 2008), subsequently recognized by Secretary of HHS as required standard for health information technology

Phase 2 – ONC collaborates with the California Health Care Foundation and HL7 to:

- » Harmonize initial IG and ELINCS to support national requirements
- » Incorporate lessons learned and feedback on both IGs and insights from the IHE Laboratory Technical Framework
- » Provide guidance and collect requirements for Lab Orders IG effort to ensure end-to-end exchange
- » Ensure support of new Meaningful Use requirements

Result is HL7 Lab Results Implementation Guide (LRI) R1

- » Supported MU Stage 1
- » IG was balloted through the HL7® process and received significant feedback
- » Begins to adopt modularity concepts for defining context specific usage on a common model
- » Includes first major focus on detailed vocabulary requirements

Initiative Summary And Kept Going...

Phase 3 – Continue to revise the LRI to support subsequent stages of Meaningful Use:

- » Incorporated new design approach to define foundational concepts applicable to all use cases
- » Profiles and Components to support specializations for new use cases based on a common universal message structure, offering tremendous flexibility on primary interface.
- » Encourages unique identifiers (OIDs) for stronger provenance and simplified identification

Also began development of Lab Orders Implementation Guide (LOI)

- » New territory... but process and architecture established with LRI allowed for rapid and synchronized development
- » Incorporates all CLIA requirements for orders
- » Provides guidance on distribution to non-ordering providers to establish limitations and expectations with current security and patient confidentiality requirements.
- » IG was balloted through the HL7® process and received significant feedback
- » R1 is published and efforts now turn toward full harmonization

Initiative Summary And Going ...

Phase 4 – The American Clinical Laboratory Association (ACLA) and ONC collaborate on integration and harmonization of ACLA Test Compendium Implementation Guide with LRI and LOI

- » In 2009 ACLA launched a project to define a standard for the electronic delivery of a laboratory's directory of services, publishing their initial IG in 2011. The effort continued in 2012 under the ONC S&I Framework with additional support from the California Health Care Foundation.

Lab US Realm WG established a sub-committee to focus on development of the eDOS implementation guide that:

- » Is harmonized with the LOI and LRI on use of LOINC and local ordering codes
- » Provides detailed information related to Ask at Order Entry questions
- » Supports definition of customized panels to ease order entry by provider but the order communicates codes the lab understand
- » Allows for additional special instructions to be communicated such as specimen collection parameters
- » Supports full, partial, or custom updates as agreed to by partners

In 2016, ACLA collaborated with ONC to create a [calculator](#) to help organizations estimate potential savings with eDOS, highlighted in [Steve Posnack's blog](#) (11/18/2016).

Initiative Summary And Going ...

Phase 5 – Synchronization and Expansion

- » Objective was to synchronize the update of all IGs to ensure new use cases are supported in the end-to-end exchange
- » Re-sync with IHE Laboratory Technical Framework
- » New use cases prioritized for inclusion and incorporated in January and May 2017 ballots
 - Newborn Dried Bloodspot Screening, incorporating the work of of Public Health Informatics Institute (PHII)
 - Clinical Genomics, incorporating the work of the HL7 Clinical Genomics workgroup with support from the National Institute of Health (NIH)
 - Public Health Reporting, fully integrates the requirements and replaces the HL7 Electronic Lab Reporting to Public Health IG (ELR)
- » Launched EHR-System Functional Requirements activity to define EHR-S behaviors relative to the receipt and processing of laboratory results messages
 - Defined storage and display requirements to ensure CLIA and sending laboratory requirements are supported
 - Detailed analysis to determine failure modes and appropriate system responses
- » Differentiation between report of record handling vs integrating results into graphs, flow charts etc.

Initiative Summary

Lab US Realm – Value Proposition

Feature	Value Proposition
Modularity	<ul style="list-style-type: none"> • Defines a common message structure and requirements for all lab orders and results • Components allow further constraints to be declared for specific use cases
Value Sets	<ul style="list-style-type: none"> • Context-specific declaration of values for each location in the message • Harmonized across the entire suite of IGs • Managed as a separate set of artifacts to allow growth in values without constantly revising the IGs
Suite of IGs	<ul style="list-style-type: none"> • Supports the full life-cycle of LIS/EHR-S interactions • eDOS – Lab communicates order codes and requirements for specimen and other clinical information to EHR-S • LOI – communicates an order from EHR-S to the LIS using values and requirements for AOE • LRI – delivers the results from the LIS to the EHR-S • LRI EHR-S FR defines EHR-S behavior for receiving and displaying results including error handling • Both LOI and LRI support CLIA requirements
Acknowledgements	<ul style="list-style-type: none"> • Defined system and application level acknowledgement behaviors and limitations • With EHR-S FR, defines EHR-S behavior and requirements for error management to ensure transmission status is as un-ambiguous as possible within a given infrastructure and trust domain.

Looking Forward

Farrah Darbouze, *Public Health Analyst, Office of Standards and Technology*

eDOS IG

- » Provides for efficient distribution of standardized and local codes for orders
 - Supports incremental harmonization of common order codes (LOINC) and mapping to local codes
 - Automates data loading, reducing time while improving accuracy

LOI IG

- » Defines the minimum requirements for lab order message content and value sets
- » Defines the requirements for lab order message structures and use

LRI IG

- » Defines the minimum requirements for lab results message content and value sets
- » Defines the requirements for lab result message structures and use

EHR-S FR IG

- » Defines the behaviors of an ERH-S upon receipt of laboratory results including definitions for hard and soft errors and their processing requirements, as well as the storage and display requirements for all other data elements

Value Set Companion Guide

- » Defines a method for representing and managing discrete value sets
- » Independent update cycle to optimize introduction of new codes

Looking Forward Lab US Realm IGs and Beyond

While the ONC's role in sponsoring and facilitating the development of Lab US Realm IGs is complete, industry's work continues to refine the requirements and expand support for specialized use cases. We are excited to see the transition of US realm focus from an ONC-sponsored project to an industry-lead standards and interoperability activity with expansion to support New Born Screening, Public Health Reporting, Clinical Genomics testing. We look forward to the next stages to address gaps for acute care and other settings, further reducing variation and implementation costs.

Stay involved by:

- » Participating in HL7[®] and its Work Group Meeting sessions
 - Building on the work of US Realm and its adoption
- » Providing feedback to HL7[®] on implementation experiences and lessons learned

<http://www.hl7.org/>

Closing Remarks

Farrah Darbouze, *Public Health Analyst, Office of Standards and Technology*

Closing Remarks
Special Thanks

THANK YOU!

Closing Remarks

Special Thanks

* Past or current co-chair of contributing work groups or Lab sub-group

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Ron Van Duyne
Kathy Walsh
Ye Wang
Rhonda West
Grant Wood
Heather Wood
Maggie Wright
Bob Yench
Careema Yusuf

And so many more...

Closing Remarks

Useful Links

Lab US Realm Wiki Homepage:

- » <https://oncprojecttracking.healthit.gov/wiki/display/TechLabSC/Lab+US+Realm>
- » Past meeting minutes are linked at the bottom of the page

Implementation Guides

- » [HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2 - US Realm \(eDOS\)](#)
- » [HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1, DSTU Release 2 - US Realm \(LOI\)](#)
- » [HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1, DSTU R2 – US Realm \(LRI\)](#)
- » [HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 1- US Realm](#)
- » [HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1 - US Realm](#)
- » [HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2, DSTU R1.1 - US Realm](#)

Closing Remarks

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